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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/152,059	09/11/1998	JESPER WENGEL	WENGEL-8	8703

7590

06/28/2002

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EXAMINER

RILEY, JEZIA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 06/28/2002

31

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

09/152,059

Applicant(s)

WENGEL ET AL.

Examiner

Jezia Riley

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 December 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 141-186, 193 and 195-208 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 193, 195, 196 is/are allowed.
- 6) ☒ Claim(s) 141-186 and 197-208 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 31.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 141-186, 197-208 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific moiety "LNA" as defined in the examples and Figures, does not reasonably provide enablement for any of "LNA" moiety falling within the instant definition. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. There is insufficient guidance in the specification as to make and use the claimed compounds for any "LNA" moiety as defined.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 112, first paragraph, have been described in *In Re Colianni*, 195 USPQ 150 (CCPA 1977) and have been adopted by the Board Appeals and Interferences in *Ex Parte Forman*, USPQ 546 (BPAI 1986).

Among these factors are: the nature of the invention, the state of the prior art, the predictability or lack thereof in the art, the breadth of the claims, the amount of direction or guidance present, and the presence or absence of working examples.

Breadth of the claims:

The claims are broadly drawn to oligomers comprising LNA nucleoside of the general formula I. Said "LNA" is very broadly defined and therefore reads on a enormous variety of compounds.

Amount of direction/guidance

A broad possible range for the "LNA" moiety is possible and in order to enable the selection of "LNA" there is a need to set forth experimental procedure to be used. It is undue experimentation to synthesize any "LNA", to determine the ones that would be used to prepare the oligomer as claimed in order to practice the broad scope of claim 141 for example. This is clearly an invitation to experiment to select "LNA" to make it specific to prepare said oligomer. These leave the entire work of synthesizing "LNA" up to someone wishing to practice claim 141 which is undue experimentation. The specification gives no guidance to permit one of skill in the art to devise strategies for synthesis of the compounds as claimed except for the ones in the Figures. The compounds that are disclosed in the instant specification all have a common structure where the biradical is a maximum of 4 atoms and comprises only C, O, or Si. One of ordinary skill in the art would not know how to make any oligomers that comprise the moiety "LNA" as broadly defined, and how to determine that such a compound would satisfactorily be useful in the antisense approach.

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Therefore given the unpredictability of the art and the lack of guidance in the specification, it is the Examiner's position that one skilled in the art could not make and use the oligomers of the claims as broadly recited without undue experimentation.

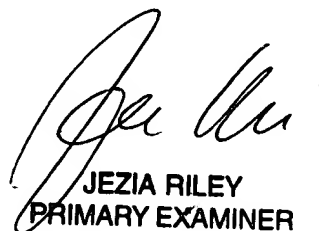
2. Claims 193, 195, and 196 are allowed.

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jezia Riley whose telephone number is 703-305-6855. The examiner can normally be reached on 9:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Patent Analyst whose telep receptionist whose telephone number is 703-308-0196.

June 25, 2002



JEZIA RILEY  
PRIMARY EXAMINER